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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/121,017	07/22/1998	TORU IMAMURA	382.1019	2849

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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. 09/12,017	Applicant(s) IMAMURA et al
Examiner SAUNDERS	Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 4/13/05
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 6, 14, 18-20, 23-30, 34-37 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 30, 34-37 is/are allowed.
- ☒ Claim(s) 1, 6, 14, 18-20, 23-29 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 9/7/04
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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The amendment of 4/13/05 had been entered claims 1, 6, 14, 18-20, 23-30 and 34-37 are pending and under examination.

The following correction pertains to the Office action of 1/10/05:

At page 4, third paragraph, first line thereof "20" should have been - - 21 - -.

The amendment filed 4/13/05 has overcome all previously stated objections to claims 3, 20 (21 intended) and 31-33 under 37 CFR 1.75 c) (page 4) and to claims 4-5 under 37 CFR 1.175 c) at page 5.

The amendment has overcome 112, second paragraph rejections of record, as they pertain to the recitations of "activity" in claims 1, 3-6, 18-21, 23-27 and 30 (intended to have been listed). The amendment has overcome the second paragraph rejection of claim 30 for reciting an improper Markush group.

Rejections under 112, first and second paragraphs are maintained/ modified with respect to the amended claims as follows:

Claims 1, 6, 14, 18-20 and 23-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitations of "wherein the at least one sugar chain is covalently bonded to a peptide at the N-terminal..." in claims 1 and 18 are unclear, because it is not clear what this "peptide at the N terminal" is. Is it an additional peptide added to the N-terminal of SEQ ID NO: 1 etc? Is it an N-terminal peptide segment within SEQ ID NO: 1 etc, and if so what are the boundaries of the N-terminal? Like considerations apply to the recitations of "wherein the sugar claims are covalently bonded to a peptide at the N-

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terminal..." in claim 19 and of "a peptide sequence at the N-terminal of said SEQ ID NO:" in claim 20.

The rejection of claim 23 is maintained for reasons of record, because applicant has done nothing to indicate where, in the recited sequences, the sugar chain(s) is covalently bonded.

As the examiner has previously noted, it is considered that each of SEQ ID NOS: 1, 17, 19, 21 and 23 consist of an N terminal segment, which consists of a part of human ryudocan, and a C terminal segment which consists of human FGF-1 and that it is the ryudocan segment which provides the sites for glycosylation. Therefore, the "peptide a N-terminal" to which "the at least one sugar chain is covalently bonded" would be properly defined as consisting of residues 1-87 for SEQ ID NO: 1, residues 1-66 for SEQ ID NO: 17, residuss 1-66 for SEQ ID NO: 19, residues 1-120 for SEQ ID NO: 21, and residues 1-147 for SEQ ID NO: 23.

The examiner considers that the "Asn" residue following these segments constitutes the start of the FGE-1 segment, at the C-terminal; clarification is requested.

With respect to SEQ ID NO: 29 recited in claims 1 and 18-20, the examiner deems that the recitation of "a peptide at the N-terminal" does not correspond to the peptide that is to have the sugar chain(s) "covalently bonded thereto". As previously stated, the examiner understands that SEQ ID NO: 29 consists of two fused segments consisting of a portion of FGF-6, from residues 1-40, and a portion of FGF-1, from residues 41-180. The examiner does understand where the glycosylation occurs; is it in

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the FGF-6 segment? If so, then the claims must define the "peptide at the N-terminal" as consisting of residues 1-40 of SEQ ID NO: 29.

Claims 1, 6, 14, 18-20, 24 and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite new matter.

As noted supra, in the indefiniteness rejection, claims 1 and 18-20 are ambiguous in that they can be interpreted as having an additional peptide, which is added to the N-terminal of the recited SEQ ID NOS: and which serves as the peptide to which the sugar chain(s) becomes covalently bonded. This embodiment is not supported by applicant's disclosure, since it is an N-terminal ryudocan segment within the recited SEQ ID NOS: that is the peptide to which the sugar chain(s) become covalently bonded. Note again, it is not clear to the examiner where the sugar chain(s) is bonded within SEQ ID NO: 29; however, the examiner finds nothing in the disclosure which would support the bonding of the sugar chain(s) to an additional peptide added to the N-terminal of SEQ ID NO: 29.

Applicant's arguing filed on 4/13/05 has been considered but have not overcome the indefiniteness and new matter issues.

Applicant is advised that should claim 1 be found allowable, claims 18 and 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

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claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The examiner sees no substantial differences between claims 1, 18 and 20. They recite the same Markush group of SEQ ID Nos and the same Markush group of sugar chains. They require the same increase in DNA synthesis promoting activity. They require that the sugar chain(s) be covalently bound to "a peptide at the N terminal" of the recited SEQ ID NOS. The claims only differ in the order in which these features are stated; a difference in ordering the recitation of the features makes for no physical/chemical difference in the nature of the functionalized heparin binding protein. Many rounds of amendment have rendered claims previously of different scope to now be of the same scope.

Claim 20 is objected to because of the following informalities: In claim 20, line 3 "NO." should be recited as -- NO: --. Appropriate correction is required.

Attached to this action is a signed copy of form 1449, filed on 9/7/04. If applicant has already received a signed copy, this is provided again, in order that there will be an imaged copy thereof in the IFW record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644

Saunders/LR  
June 23, 2005